

We claim:

1. A method for the local treatment of a vulvovaginal candidiasis condition diagnosable by a KOH smear test or other fungal speciation test, which comprises:

treating said vulvovaginal candidiasis condition caused by a species of *Candida* selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae* by applying to the vaginal tissue of a human a formulation comprising:

about 35 to about 45% w/w sorbitol solution; about 3 to about 8% w/w propylene glycol; about 0.001 to about 1% w/w edetate disodium; about 5 to about 11% w/w mineral oil; about 0.5 to about 5% w/w polyglyceryl -3- oleate; about 0.5 to about 5% w/w glyceryl monoisostearate; about 0.001 to about 1% w/w microcrystalline wax; about 0.5 to about 2% w/w silicon dioxide; about 0.001 to about 1% w/w methylparaben; about 0.001 to about 1% w/w propylparaben; about 25 to about 45% w/w water; and about 0.5 to about 5% w/w butoconazole nitrate; and

wherein the treatment is a single dose treatment.

2. The method according to claim 1, wherein said formulation further comprises:

about 38 to about 40% w/w sorbitol solution; about 4 to about 6% w/w propylene glycol; about 0.01 to about 0.5% w/w edetate disodium; about 6 to about 9% w/w mineral oil; about 2 to about 3% w/w polyglyceryl -3- oleate; about 2 to about 3% w/w glyceryl monoisostearate; about 0.01 to about 0.8% w/w microcrystalline wax; about 0.09 to about 0.9% w/w silicon dioxide; about 0.01 to about 0.5% w/w methylparaben; about 0.01 to

about 0.5% w/w propylparaben; about 30 to about 40% w/w water; and about 1.5 to about 3.5% w/w butoconazole nitrate.

3. The method according to claim 2, wherein said formulation further comprises:

about 39.978% w/w sorbitol solution; about 5% w/w propylene glycol; about 0.05% w/w edetate disodium; about 8.032% w/w mineral oil; about 2.713% w/w polyglyceryl -3- oleate; about 2.713% w/w glyceryl monoisostearate; about 0.452% w/w microcrystalline wax; about 1.013% w/w silicon dioxide; about 0.18% w/w methylparaben; about 0.05% w/w propylparaben; about 37.819% w/w water; and about 2.0% w/w butoconazole nitrate.

4. The method according to claim 3, wherein the species is *C. glabrata*.

5. The method according to claim 3, wherein the species is *C. tropicalis*.

6. A method for the treatment of a vaginal fungal condition, which comprises:

administering a single dose composition comprising about 38 to about 40% w/w sorbitol solution; about 4 to about 6% w/w propylene glycol; about 0.01 to about 0.5% w/w edetate disodium; about 6 to about 9% w/w mineral oil; about 2 to about 3% w/w polyglyceryl -3- oleate; about 2 to about 3% w/w glyceryl monoisostearate; about 0.01 to about 0.8% w/w microcrystalline wax; about 0.09 to about 0.9% w/w silicon dioxide; about 0.01 to about 0.5% w/w methylparaben; about 0.01 to about 0.5% w/w

propylparaben; about 30 to about 40% w/w water; and about 1.5 to about 3.5% w/w butoconazole nitrate;

wherein the vaginal fungal condition is a vulvovaginal candidiasis condition caused by a *Candida* species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*, and

wherein the ratio of polyglyceryl – 3- oleate to glyceryl monoisostearate is about 1:0.1-10.

7. The method according to claim 6, wherein the species is *C. glabrata*.

8. The method according to claim 6, wherein the species is *C. tropicalis*.

9. A method for the treatment of an unidentified vulvovaginal fungal condition, which comprises:

administration to said fungal condition a bioadhesive, single dose treatment formulation comprising from about 0.500 to about 5.000% w/w butoconazole nitrate; and

wherein the unidentified vulvovaginal fungal condition is caused by a *Candida* species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*.

10. The method according to claim 9, wherein said formulation further comprises: about 35 to about 45% w/w sorbitol solution; about 3 to about 8% w/w propylene glycol; about 0.001 to about 1% w/w edetate disodium; about 5 to about 11%

w/w mineral oil; about 0.5 to about 5% w/w polyglyceryl -3- oleate; about 0.5 to about 5% w/w glyceryl monoisostearate; about 0.001 to about 1% w/w microcrystalline wax; about 0.5 to about 2% w/w silicon dioxide; about 0.001 to about 1% w/w methylparaben; about 0.001 to about 1% w/w propylparaben; about 25 to about 45% w/w water; and about 0.5 to about 5% w/w butoconazole nitrate.

11. The method according to claim 10, wherein said formulation further comprises:

about 38 to about 40% w/w sorbitol solution; about 4 to about 6% w/w propylene glycol; about 0.01 to about 0.5% w/w edetate disodium; about 6 to about 9% w/w mineral oil; about 2 to about 3% w/w polyglyceryl -3- oleate; about 2 to about 3% w/w glyceryl monoisostearate; about 0.01 to about 0.8% w/w microcrystalline wax; about 0.09 to about 0.9% w/w silicon dioxide; about 0.01 to about 0.5% w/w methylparaben; about 0.01 to about 0.5% w/w propylparaben; about 30 to about 40% w/w water; and about 1.5 to about 3.5% w/w butoconazole nitrate.

12. The method according to claim 10, wherein said formulation further comprises:

about 39.978% w/w sorbitol solution; about 5% w/w propylene glycol; about 0.05% w/w edetate disodium; about 8.032% w/w mineral oil; about 2.713% w/w polyglyceryl -3- oleate; about 2.713% w/w glyceryl monoisostearate; about 0.452% w/w microcrystalline wax; about 1.013% w/w silicon dioxide; about 0.18% w/w

methylparaben; about 0.05% w/w propylparaben; about 37.819% w/w water; and about 2.0% w/w butoconazole nitrate.

13. The method according to claim 12, wherein the species is *C. glabrata*.

14. The method according to claim 12, wherein the species is *C. tropicalis*.

15. The method according to claim 10, wherein the bioadhesive formulation minimizes leakage from the vaginal cavity of a human.

16. The method according to claim 10, wherein the treatment provides peak plasma levels of the butoconazole nitrate at about 6 to about 48 hours after administration and retains activity for at least 4 days.

17. A method for the treatment of a fungal condition diagnosable by KOH smear test or other fungal speciation test, which comprises:

application to a vulvovaginal candidiasis condition caused by a member selected from the group consisting of *Candida dubliniensis*, *Candida tropicalis*, *Candida glabrata*, *Candida parapsilosis*, mycelial *Candida*, *Candida krusei*, and *Candida lusitaniae* and mixtures thereof of a treatment comprising:

about 35 to about 45% w/w sorbitol solution; about 3 to about 8% w/w propylene glycol; about 0.001 to about 1% w/w edetate disodium; about 5 to about 11% w/w mineral oil; about 0.5 to about 5% w/w polyglyceryl -3- oleate; about 0.5 to about 5%

w/w glyceryl monoisostearate; about 0.001 to about 1% w/w microcrystalline wax; about 0.5 to about 2% w/w silicon dioxide; about 0.001 to about 1% w/w methylparaben; about 0.001 to about 1% w/w propylparaben; about 25 to about 45% w/w water; and about 0.5 to about 5% w/w butoconazole nitrate.

18. The method according to claim 17, wherein the treatment is a single dose treatment.

19. A method for the local treatment of an unidentified vaginal fungal condition comprising:

a single administration of a composition consisting essentially of: about 38 to about 40% w/w sorbitol solution; about 4 to about 6% w/w propylene glycol; about 0.01 to about 0.5% w/w edetate disodium; about 6 to about 9% w/w mineral oil; about 2 to about 3% w/w polyglyceryl -3- oleate; about 2 to about 3% w/w glyceryl monoisostearate; about 0.01 to about 0.8% w/w microcrystalline wax; about 0.09 to about 0.9% w/w silicon dioxide; about 0.01 to about 0.5% w/w methylparaben; about 0.01 to about 0.5% w/w propylparaben; about 30 to about 40% w/w water; and about 1.5 to about 3.5% w/w butoconazole nitrate.; and

wherein the administration is to a vulvovaginal candidiasis condition caused by any member selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*.

20. The method according to claim 19, wherein the species is *C. glabrata*.

21. The method according to claim 19, wherein the species is *C. tropicalis*.

22. A method for the treatment of a fungal condition diagnosable by KOH smear test or other fungal speciation, comprising:

treating a candidiasis condition caused by a species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae* by applying to the vaginal tissue a multiphase formulation in a single dose;

wherein the multiphase formulation comprises:

a hydrophilic phase, which comprises: about 38 to about 40% w/w sorbitol solution; about 3 to about 8% w/w propylene glycol; about 0.001 to about 1% w/w edetate disodium; about 25 to about 45% w/w water; and about 0.5 to about 5% w/w butoconazole nitrate; and

a hydrophobic phase which comprises about 5 to about 11% w/w mineral oil; about 0.5 to about 5% w/w polyglyceryl -3- oleate; about 0.5 to about 5% w/w glyceryl monoisostearate; about 0.001 to about 1% w/w microcrystalline wax; about 0.5 to about 2% w/w silicon dioxide; about 0.001 to about 1.000% w/w methylparaben; and about 0.001 to about 1% w/w propylparaben.

23. The method according to claim 22, wherein the hydrophobic phase and hydrophilic stage for a bioadhesive dosage form provides peak plasma levels of butoconazole nitrate at about 6 to about 48 hours and retains activity for at least 4 days.

24. A method for the treatment of an undiagnosable vulvovaginitis condition comprising:

treating a condition caused by a species of *Candida* selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae* by applying to the vaginal tissue a multiphase formulation in a single dose to provide a *Candida* species kill rate of about 50 to about 100% for a period of at least about 4 days.

25. The method according to claim 24, wherein the multiphase formulation is administered via an applicator device which is designed to apply the formulation evenly over the vaginal tissue of a human.

26. A method according to claim 24, wherein the species is *C. glabrata*.

27. A method according to claim 24, wherein the species is *C. tropicalis*.